Docket No. BIO5044USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Assaf Govari	Confirmation No.:	4469
Appln. No.	:	10/807,979		
Filed	:	March 24, 2004		
Title	:	PHASED-ARRAY FOR TISSUE TREATMENT		
Art Unit	:	3739		
Examiner	:	Vrettakos, Peter J.		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

i. Real Party in Interest

Biosense Webster, Inc., a California Corporation, is the real party in interest.

ii. Related Appeals and Interferences

None.

iii. Status of Claims

Claims 1 and 4 - 11 are pending in the case. Claims 1 and 4 – 11 have been finally rejected on September 5, 2006 and this Appeal is taken from these claims.

iv. Status of Amendments

No Amendments have been filed subsequent to the Final Rejection mailed on September 5, 2006.

v. Summary of Claimed Subject Matter

As fully supported in Applicant's Specification, the claimed present invention of independent Claim 1 is directed to an apparatus for use with a subject comprising a catheter 10 having a longitudinal axis and a distal portion as shown in FIG. 1; and an ultrasound array 32 (FIG. 2) comprising between about thirty-two (32) and sixty-four (64) ultrasound transducers 34 circumferentially arranged around the longitudinal axis at the distal portion. Applicant's Specification Page 16, Lines 3 – 19. The ultrasound array 32 with its separate transducers 34 (totaling between 32 – 64 different ultrasound transducers) are adapted to operate in a phased array mode to apply ablating energy to tissue of the subject located in a range of azimuths, with respect to the longitudinal axis, that is less than 360 degrees, including a range of azimuths between 180 and 359 degrees. Applicant's Specification, Page 10, Lines 21-26; Page 16, Lines 21 – 27; and FIGS. 3A and 3B.

Moreover, as clearly indicated in Applicant's Specification, the criticality of the number of transducers 34, i.e. between thirty-two to sixty-four transducers, and the range of azimuths for the applied ablating energy, i.e. range of azimuths between 180 and 359 degrees, for Applicant's claimed present invention of Claim 1 is specifically addressed in detail in Applicant's Specification, Page 16, Line 21 – Page 17, Line 33 (for the example whereby Applicant's claimed invention is particularly useful ablating regions close to the very delicate phrenic nerve in the pulmonary vein) and Page 18, Line 1 – Page 19, Line 21 (for the example whereby Applicant's claimed invention is particularly useful ablating a liver tumor). These combination of novel features clearly enable Applicant's claimed

present invention to achieve remarkable unexpected results, presently not found or even suggested in the cited prior art references. For example, see the ultrasound ablation energy profile for Applicant's phased array 32 clearly indicated in FIG. 3B which permits appropriate ablation energy to be applied to the vessel wall of the pulmonary vein and relatively less ablation energy to be applied to those tissue regions close to the phrenic nerve (a vital nerve in the pulmonary vein that must be avoided).

vi. Grounds of Rejection to be Reviewed on Appeal

1. Claims 1 and 4 – 9 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,971,394 (Sliwa, Jr. et al.).

2. Claims 10 and 11 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,971,394 (Sliwa, Jr. et al.) in view of U.S. Patent No. 6,004,269 (Crowley et al.).

vii. Argument

1. The rejection of Claims 1 and 4 – 9 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,971,394 (Sliwa, Jr. et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the

claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Turning now to the cited prior art reference, Sliwa, Jr. et al. is directed to methods and devices for ablation wherein some embodiments disclose a device 400 that delivers focused ultrasound formed at an angle of 10 to 170 degrees, more preferably, 30 to 90 degrees and more preferably about 60 degrees as defined relative to a focal axis A. Column 28, lines 33-42. Although Sliwa, Jr. et al. discloses the use of a multi-element acoustic phased array, there are no specific teachings or even suggestions relating to the number of ultrasound transducers nor a range of azimuths associated with the delivery of ultrasound energy therefrom. See also the Examiner's admission in Par. No. 9 of the Final Rejection dated September 5, 2006 that Sliwa, Jr. et al. is clearly "silent" regarding a range of azimuths such as found with Applicant's claimed present invention. Moreover, Sliwa, Jr. et al. is also particularly vague and lacks any particular guidance to one of ordinary skill in this field as to the number of ultrasound transducers that would be useful (and successful) for an ultrasound ablation in the pulmonary vein adjacent the delicate phrenic nerve.

Accordingly, the Sliwa, Jr. et al. device would be entirely incapable of achieving the unexpected ablation results of Applicant's claimed present invention for procedures such as ablation, for instance, in the pulmonary vein adjacent the phrenic nerve, etc.

Thus, one can easily ascertain that there are significant differences between the teachings of this prior art reference and the Applicant's claimed invention especially since Sliwa, Jr. et al. does not teach or suggest a combination of novel features, such as a phased array having between thirty-two and sixty-four transducers and a critical range of ablation azimuths ranging between azimuths between 180 and 359 degrees as with Applicant's claimed present invention.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As clearly taught in Sliwa, Jr. et al. "focused ultrasound…forms an angle of 10 to 170 degrees, more preferably 30 to 90 degrees and most preferably about 60 degrees …." Col. 28, Lines 39 – 42. Thus, one of ordinary skill in the ablation field would be entirely discouraged from following the path set out in the teaching Sliwa, Jr. et al. Accordingly, it is clear that this reference actually teaches away from Applicant's claimed present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp,* 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

> [t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to

combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Not only does Sliwa, Jr. et al. set forth teachings that are completely divergent from the Applicant's claimed invention (as addressed previously above), but, there is clearly no motivation in Sliwa, Jr. et al. to modify its ultrasound array to achieve the novel combination of between thirty-two to sixty-four ultrasound transducers that apply ultrasound ablation energy in a range of azimuths ranging between 180 and 359 degrees such as found with the Applicant's claimed present invention.

Accordingly, since Sliwa, Jr. et al. fails to show any teaching or motivation to modify its teachings in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that

Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

Furthermore, as is well established, prior art patents can only be used for what they clearly disclose or suggest. *In re Randol and Redford*, 425 F. 2d 1268, 165 USPQ 586, 588 (C.C.P.A. 1970). And, as set forth in *In re Randol and Redford*, it is clearly improper to use a patent as a reference for modifying its structure in a manner in which the prior art references do not suggest. Thus, just because Sliwa, Jr. et al. generally discloses that more than one ultrasound transducer can be used with its device and particularly discloses critical ablation azimuth ranges of 170 degrees and more preferably less degrees than this such as 10 degrees, it does not mean that unreasonable license should be taken with the teachings of this reference as proposed by the Examiner, i.e. an unreasonable attempt to modify this teaching in an effort to arrive at the Applicant's claimed present invention, especially when there is absolutely no indication in the limited teachings of Sliwa, Jr. et al. that such a modification (as suggested by the Examiner) could ever be feasible or even desirable.

Moreover, in cases where an Applicant narrows a claim with a limitation in order to advance prosecution, he/she should be entitled to do so without having to be required to prove criticality. *In re Luvisi and Nohejl*, 342 F.2d 102, 144 U.S.P.Q. 646, 651 (C.C.P.A. 1965). Accordingly, the Examiner in the present Application is in error for putting this requirement on the Applicant during prosecution of the present invention of the instant Application.

Furthermore, it is well established case law that purported experimentation in order to define parameters to make a device work is an application of the often rejected (by the Courts) "obvious-to-try" standard, and falls far short of what constitutes statutory obviousness in accordance with 35 USC § 103. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q. 2d 1434 (Fed. Cir. 1988).

2. The rejection of Claims 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,971,394 (Sliwa, Jr. et al.) in view of U.S. Patent No. 6,004,269 (Crowley et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

As admitted by the Examiner, Sliwa, Jr. et al. is completely "silent" regarding having imaging transducers adjacent ultrasound ablation transducers at a distal end of a catheter in conjunction with an external imaging capability located external to the patient's body such as found with Applicant's claimed present invention of Claim 10 and Claim 11.

Crowley et al. teaches catheters for imaging, sensing electrical potentials, and ablating tissue wherein its catheter includes an ultrasound device 10 for acoustic imaging. It is important to note that Crowley et al. does not specifically teach external imaging capability such as found with Applicant's claimed present invention of Claims 10 and 11, but rather, Crowley et al. specifically teaches classic electrophysiological mapping using a standard mapping electrode adjacent its ultrasound transducer at the distal end of its catheter 10. See Col. 3, Lines 52 – 57.

Thus, one can easily ascertain that there are significant differences between the teachings of this prior art reference and the Applicant's claimed invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the

art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp,* 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

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The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes

the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

As addressed above, there is clearly no motivation in Crowley et al. to modify its ultrasound catheter with electrophysiology mapping electrode in order to achieve the novel combination of imaging transducers adjacent ultrasound ablation transducers at a distal end of a catheter in conjunction with an external imaging capability located external to the patient's body such as found with the Applicant's claimed present invention of Claims 10 and 11.

Accordingly, since Crowley et al. fails to show any teaching or motivation to combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, and there is no doubt that Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

Furthermore, as is well established, prior art patents can only be used for what they clearly disclose or suggest. *In re Randol and Redford*, 425 F. 2d 1268, 165 USPQ 586, 588 (C.C.P.A. 1970). And, as set forth in *In re Randol and Redford*, it is clearly improper to use a patent as a reference for modifying its structure in a manner in which the prior art references do not suggest. Thus, just because discloses electrophysiological mapping using a mapping electrode adjacent its ultrasound transducer, it does not mean that unreasonable license should be taken with the teachings of this reference as proposed by the Examiner, i.e. an unreasonable attempt to modify this teaching in an effort to arrive at the Applicant's claimed present invention, especially when there is absolutely no indication in the limited teachings of Crowley et al. that such a modification (as suggested by the Examiner) could ever be feasible or even desirable.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

It is important to note that Crowley et al. teaches particularly:

[i]t is advantageous to have a single, multifrequency transducer rather than two different different transducers because if a single, multifrequency transducer is used the user can select at will the depth of penetration desired and the frequency of operation desired without having to shift the position of the catheter, whereas if two transducers are used it may be necessary to shift the position of the catheter unless the two transducers oppose each other on opposite sides of the drive shaft. Col. 21, Lines 10 – 19.

Accordingly, it is evident that Crowley et al. teaches at most two ultrasound transducers, and clearly states that it is most "advantageous" to have only a single transducer with its ultrasound catheter. No doubt, this teaching is clearly divergent from the thirty-two to sixty-four ultrasound transducers of Applicant's ultrasound phased array distinctly claimed in Applicant's claimed present invention.

Thus, one of ordinary skill in the ablation field would be entirely discouraged from following the path set out in the teaching Crowley et al. Therefore, it is clear that this reference actually teaches away from Applicant's claimed present invention.

Accordingly, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

Respectfully submitted,

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viii. Claims Appendix

Claim 1. Apparatus for use with a subject, comprising:

a catheter having a longitudinal axis and having a distal portion; and an ultrasound array comprising between about 32 and 64 ultrasound transducers circumferentially arranged around the longitudinal axis at the distal portion, and adapted to operate in a phased array mode to apply ablating energy to tissue of the subject located in a range of azimuths, with respect to the longitudinal axis, that is less than 360 degrees, including a range of azimuths between 180 and 359 degrees.

Claim 4. The apparatus according to claim 1, wherein when the catheter is disposed in a vicinity of an ostium of a pulmonary vein of the subject, the range of azimuths is sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve of the subject.

Claim 5. The apparatus according to claim 1, comprising detection functionality, adapted to determine tissue of the subject that is not to be targeted by the ablating energy, wherein the ultrasound array is adapted to configure the ablating energy responsive to the determination of the tissue that is not to be targeted.

Claim 6. The apparatus according to claim 5, wherein the ultrasound array is adapted to set the range of azimuths responsive to the determination of the tissue that is not to be targeted.

Claim 7. The apparatus according to claim 5, wherein the detection functionality comprises an ultrasound transducer.

Claim 8. The apparatus according to claim 5, wherein the detection functionality comprises at least a portion of the ultrasound array.

Claim 9. The apparatus according to claim 5, wherein the detection functionality comprises imaging functionality.

Claim 10. The apparatus according to claim 5, wherein the detection functionality is adapted to be fixed to the distal portion of the catheter.

Claim 11. The apparatus according to claim 5, wherein the detection functionality is adapted to operate external to a body of the subject.

ix. Evidence Appendix

Not Applicable.

x. Related Proceedings Appendix

Not Applicable.